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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,441	05/03/2005	Tomoji Maruyama	260364US90PCT	9474
22850	7590	08/04/2010	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			YABUT, DIANE D	
ART UNIT	PAPER NUMBER			
			3734	
NOTIFICATION DATE	DELIVERY MODE			
08/04/2010	ELECTRONIC			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/511,441	<b>Applicant(s)</b> MARUYAMA ET AL.
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 May 2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2,3,5-8 and 25-32 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 2,3,5-8 and 25-32 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to applicant's amendment received on 05/13/2010.

The examiner acknowledges the amendments made to the claims. Claims 2-3, 5-32 are pending in this application. Claims 9-24 are withdrawn from consideration.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2-3, 5-8 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz (U.S. Patent No. 5,814,065) in view of Modesitt et al. (U.S. Patent No. 7,001,400).

Diaz discloses providing a suturing apparatus comprising a body part ("elongated member") 15 with a predetermined length having a front side part that can be inserted into a tissue of an organism from a hole and a rear portion that cannot be inserted into said organism having a portion ("tip") 36, two hollow needle members 34 that are accommodated in a portion 18 inside said body part rearward from said tip portion (Figure 1), a needle operation portion 60 for advancing said needle members toward said tip portion from a side surface of said body part (Figure 4), two openings (extreme rear-most openings of needle operation portion 60) disposed at a rear-most portion of said body part that communicate with lumens of said two hollow needle members,

wherein said tip portion has two needle member receiving portions (either end of **38** in Figures 6-7) for receiving a distal end of one of said hollow needle members and that of the other of said hollow needle members respectively pressed out of said body part, and a connection duct **38** ("needle lumen portion" on distalmost portion of **36**) said openings through one of said lumens of one of said two hollow needle members, through said connection duct of said tip portion, and through the other of said lumens of the other of said two hollow needle members, when said two needle member receiving portions receive said hollow needle members respectively at a same time (Figures 4, 6-7). A suturing member can be inserted into said duct for a suturing thread, said suturing member including a guide portion linearly formed of an elastic material (length of "coil") **76** and a suturing thread portion **70** provided on said guide portion and the tip portion has a thread pull-out slit (on sloping external surface of **36** near **38**) extending from an upper surface thereof (see upper surface of **36** in Figure 1 where said two needle member receiving portions are located) and communicating with said two needle member receiving portions and said connection duct and being oblique to a longitudinal axis of said rotary portion and being positioned so that said thread pull-out slit is not located at a front portion of said connection duct (Figure 1). An urging member **68** urges said needle member operation portion or said hollow needle member rearward and a stopper (wide, rear portion of **60**) configured to stop said hollow needle members at a position pressed by said needle member operation portion (Figure 4).

The tip portion is inserted into a blood vessel **14** from a penetrated hole, the hollow needles are advanced to the tip portion and penetrate through the blood vessel,

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and the suturing thread **70** is passed from a proximal end of one of the hollow needles through the lumen of the hollow needle, through the needle receiving portion, through the connection or communication duct **38** in the tip portion, through the other needle receiving portion, through the lumen of the other hollow needle, and to a proximal end of the other hollow needle, and returning the hollow needle members into the body part and pulling the suturing apparatus out of the puncture site and leaving the thread (Figures 4, 6-9).

Diaz discloses the claimed invention except for the tip portion being a rotary portion rotatably supported to a front end of said body part, rotating the rotary portion in the blood vessel until the body part becomes oblique at a predetermined angle with respect to an axis of the rotary portion, returning the rotary portion back to an initial position. Diaz also lacks a rotary portion towing wire, a rotary portion side-surface opening to receive a supporting pin on said body part, or a rotation angle restriction function.

Modesitt et al. teach a suturing apparatus having a rotary portion ("articulatable foot") **24** that is rotatably supported to a front end of a body part ("shaft") **12**, that may be rotated at an oblique angle during suturing and returned back to an initial position in line with the longitudinal axis of the shaft (Figures 6A-6C). A rotary portion towing wire ("foot actuation wire") **32** extends inside said body part and is fixed to said rotary portion at one end thereof (Figure 5), wherein said body part has a supporting pin **60** for rotatably supporting said rotary portion **24i**, said rotary portion has a side-surface opening ("slot") **62** for receiving said supporting pin, formed long and axially extending

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to allow sliding of said supporting pin (Figures 8A-8C; col. 9, lines 22-30). The rotation angle restriction function permitting a rotation of said rotary portion between a state in which said rotary portion is on an approximate extension line of an axis of said body part and a predetermined angle less than 90 degrees may be considered to be the length of the side-surface opening. Although Modesitt et al. does not expressly restrict the rotation to be at a predetermined angle less than 90 degrees, it would have occurred to one of ordinary skill in the art to limit the range of movement since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotary portion to Diaz, as taught by Modesitt et al., in order to provide more flexibility of movement in positioning the tip portion to the vessel wall, while still avoiding dilation of the puncture (col. 4, lines 1-17).

#### ***Response to Arguments***

3. Applicant's arguments filed 05/13/2010 have been fully considered but they are not persuasive.
4. Applicant argues that Diaz fails to describe second needle lumen portions 38 extend from an upper surface of a rotary portion and communicate with two needle receiving portions since the needle lumen portions 38 are formed along the side and bottom of the tip 36. The examiner disagrees. As seen in Figure 1, the tip 36 contains

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an upper surface that clearly shows the second lumen portions extending from an upper surface thereof.

5. Applicant also argues that Diaz does not disclose first needle lumens **28** communicating with second needle lumen portions **38** since there is a gap between them. However, the gap allows communication between the first and second needle lumen portions when the first and second needles are disposed therethrough.

6. Lastly, applicant argues that Diaz does not disclose second needle lumen portions **38** that are oblique to a longitudinal axis of the rotary portion, but are rather parallel. However, the thread pull-out slit is recited as "oblique" and not the second needle portions. The thread pull-out slit cited by the examiner is on the sloping external surface of **36** near **38**) between the two needle receiving portions (either end of **38** in Figures 6-7) and the connecting duct ("needle lumen portion" on distalmost portion of **36**).

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/TODD E. MANAHAN/  
Supervisory Patent Examiner, Art Unit 3734